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To statin or not to statin? Report offers physicians tips to help patients make the right call

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Cholesterol-lowering statins have transformed the treatment of heart disease. But while the decision to use the drugs in patients with a history of heart attacks and strokes is mostly clear-cut, that choice can be a far trickier proposition for the tens of millions of Americans with high cholesterol but no overt disease.

Now a report from preventive cardiologists at Johns Hopkins and elsewhere offers a set of useful tips for physicians to help their patients make the right call.

The report, published March 30 in the *Journal of the American College of Cardiology*, combines the experts' collective clinical wisdom with previously published research on the benefits and potential downsides to long-term statin use.

"Given that heart disease tops mortality charts as the number one-killer of Americans, 'to statin or not to statin' is one of the most important questions faced by patients and physicians alike," says lead author Seth Martin, M.D., M.H.S., an assistant professor of cardiology at the Johns Hopkins University School of Medicine and the Johns Hopkins Ciccarone Center for the Prevention of Heart Disease. "Our report offers concrete tips for clinicians on how to conduct this vital discussion and to reduce patient uncertainty and frustration in making this complicated decision."

Atherosclerotic heart disease—the most common form of the disease—develops gradually as fat builds inside the blood vessels and makes them stiff, narrowed and hardened over time, greatly reducing their ability to supply oxygen-rich blood to the heart muscle and brain. Statins work by lowering the amount of circulating cholesterol in the blood and halting or slowing the formation of dangerous fatty plaque. Rarely, however, statins can precipitate the onset of other serious conditions, including muscle damage and diabetes. The risk of such infrequent side effects pales in comparison with the very real risk of heart attack or stroke among those with established heart disease or history of stroke. However, the risk-benefit balance is much trickier to gauge among those who have no actual disease but whose high cholesterol and other risk factors render them likely yet not definite candidates for heart attacks and strokes.

The latest guidelines from the American Heart Association and the American College of Cardiology, state that in those with high cholesterol but no overt heart disease, the decision to start preventive statins—typically as a lifelong therapy—should factor in a patient's likelihood of suffering a heart attack or stroke over the next decade among several other variables. The guidelines recommend "considering" preventive therapy in those whose 10-year risk score for suffering a heart attack or stroke is 7.5 percent or higher, but they leave a lot of room for variation, the authors of the report say.

"That decision should be informed by the intersection of scientific evidence, clinical judgment and patient preference, but clinicians need to individualize the advice," says study author Neil J. Stone, M.D., Bonow Professor of Medicine/Cardiology at Northwestern University's Feinberg School of Medicine.

Making the right choice, the experts say, hinges on the physician's clear explanation—and the patient's correct understanding—of the benefits

and risks of statins as they pertain to that specific patient, not as an obscure statistical concept.

"It's a simple concept: making sure we're not treating the disease but the person with the disease, and, in this case, those at elevated risk for it," Martin says. "Done the right way, this is precision medicine at its best."

Tips for clinicians on having "the statin" conversation:

- Don't get fixated on a number. In recent years, a patient's cardiovascular risk score has emerged as the guiding factor in clinical decision-making about preventive statins. The score, which measures the likelihood for having a heart attack or stroke over 10 years, is determined by plugging multiple variables, such as age, gender, race, blood pressure and cholesterol levels, into a clinical "calculator." But, the authors warn, the risk score should not be used as a shortcut to expedite decisions. Instead, it should be a conversation starter, particularly in light of recent findings that calculators used to determine the score tend to overestimate risk. Patients with borderline scores may benefit from additional testing, including coronary calcium CT scans, which can clarify their risk further.

The Johns Hopkins team urges clinicians to ask patients to use the risk-score calculator prior to their visit and come armed with questions.

- Shared decision-making doesn't mean split decision-making. Giving patients a choice and ensuring they have the final say in treatment decisions is laudable, but research shows that patients often want their physicians to take the lead on problem-solving, Martin advises.
- When there's no time, make the time. Working under the tyranny of 15-minute appointments can severely limit a physician's

ability to have a meaningful conversation, but that talk needn't happen over a single visit. "Given that one in three of their patients will die of heart attack or stroke, it's critical that physicians make time for a comprehensive conversation about statins, even if that means spreading out the conversation over several visits," Martin says.

- Contextualize risk. A patient cannot make the right treatment choice without a clear understanding of what's at stake. When discussing a patient's risk, don't just throw out numbers. One way to provide meaningful perspective is to compare a patient's likelihood of suffering a heart attack or stroke to someone of the same age, gender and race who has optimal risk factors. In addition, clinicians should take care to emphasize that risk scores are based on average outcomes among patients with similar risk factors but that they are not perfect predictors of individual risk.
- The five M's of statin use: In their conversations with patients, physicians should discuss the 5M's of statin side effects: memory, metabolism, muscle, medication interaction and major organ effects. Address each one individually. Use simple arithmetic to convey the difference between expected therapeutic value versus possible harm as a net benefit.
- Statins and diabetes. Statin use has been linked to a higher risk of developing diabetes because the medication can fuel mild glucose elevations in predisposed individuals—an effect that can often be countervailed by exercise and losing as little as a few pounds. Explain to patients that cholesterol-lowering drugs tend to unmask underlying diabetes and hasten its onset in those predisposed to it. People with pre-diabetes should only be treated with statins if they have a markedly elevated risk of heart attack and stroke. Emphasize to patients that even those who develop diabetes after starting statin therapy derive the same or even greater benefits in terms of reducing their cardiovascular risk.
- Statins and memory. Reassure patients that there is very little

evidence—most of it unconvincing—that statins impair memory function. In fact, research suggests that statins may help preserve memory by warding off strokes.

- Statins and muscles. Assure patients that severe muscle damage from statin use is exceedingly rare, but that minor aches and pains are common yet often benign. Reassess muscle function within three months after statin initiation and urge patients to report any new or worsening muscle pain.
- Aim for the highest tolerable dose. To obtain maximum benefit, aim for the highest dose tolerable in those without predisposition for side effects. Use lower doses in people predisposed to side effects or taking medications that could interact with statins.
- Pay attention to news media. Periodically scan major news headlines about statins and heart disease.

"News stories can and do shape patient perceptions of risk," Martin says. "Understanding what messages patients are exposed to can give physicians valuable insights about their main concerns and worst fears, and it help them address these head on."

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